REMARKS

Claim 34 is the sole active claim. Claim 35 has been cancelled to reduce the number of issues on appeal. The invention is now directed solely to the treatment of stuttering.

Claims 34 and 35 stand rejected under 35 U.S.C. 103(a) over Doble et al. in view of Novo Nordisk and Sandyk.

Doble et al. teaches that pagoclone is a partial agonist of $GABA_A$ receptor. The Examiner concedes that the reference does not teach administration of pagoclone for treating stuttering. The obviousness rejection is based on Novo Nordisk, for teaching that stuttering is a disorder which is (somehow) "related to GABA uptake activity (See abstract)" [Office Action page 2, lines 3 – 4 from bottom], and Sandyk, which teaches that changes in the synthesis and release of GABA itself can improve dysarthria stuttering. The supporting references do not suggest using pagoclone to treat stuttering or provide any motivation to focus on this particular "partial agonist of $GABA_A$ receptor." Therefore, this is an 'obvious-to-try" rejection, in which the examiner has not shown there would have been a reasonable expectation of success, and, therefore, does not meet the test of obviousness under 35 U.S.C. 103(a). *In re Vaeck* 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

The application contains an account of the clinical study that lead to the discovery of pagoclone's effectiveness for treating stuttering. Example 6.1, starting on page 20, is not a prophetic example; however, Examples 6.2 and 6.3 are prophetic.

The study was a double blind placebo-controlled clinical trial on the safety and efficacy of pagoclone for the treatment of Panic Disorder, a form of anxiety disorder, which was conducted under Dr. Murphy's (an inventor) direct supervision and control.

A twenty-six-year old female patient with a severe stuttering problem was enrolled in that study and experienced a significant reduction in stuttering during the trial, while taking 0.60 mg pagoclone/day, although that information was concealed until the end of the trial. Both she and the treating clinician noticed this reduction in stuttering and first documented it during week two of the trial.

Upon further investigation Dr. Murphy learned that this patient had previously taken other anti-anxiety medications for her psychiatric condition but had never experienced this sort of effect on her stuttering before. Shortly after the trial concluded, her stuttering problem returned to its pre-drug levels of severity.

At that time (and even today) there were no FDA approved drugs for the treatment of stuttering. This result was unexpected and could not have been predicted with a reasonable chance of success for the general teachings about the role of GABA in stuttering found in Doble as modified by Novo Nordisk

and/or Sandyk. Accordingly, the present invention would not have been obvious withing the meaning of 35 USC 103(a).

No additional fees are believed to be necessary. However, the Commissioner is authorized to charge any shortage in fees due in connection with the filing of this communication, or credit any overpayment, to Deposit Account No. 50-1710.

Respectfully submitted,

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